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| APPLICATION NO. | FILING DATE | FIRST NAMED INVENTOR | ATTORNEY DOCKET NO. | CONFIRMATION NO. |
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| 09/995,593 | 11/29/2001 | Seiji Sakano | KP8447DIV | 2953 |

466 7590 08/30/2004
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EXAMINER

MERTZ, PREMA MARIA

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| ART UNIT | PAPER NUMBER |
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1646

DATE MAILED: 08/30/2004

Please find below and/or attached an Office communication concerning this application or proceeding.

Office Action Summary

Application No.

09/995,593

Applicant(s)

SAKANO ET AL.

Examiner

Prema M Mertz

Art Unit

1646

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If the period for reply specified above is less than thirty (30) days, a reply within the statutory minimum of thirty (30) days will be considered timely.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

- 1) ☒ Responsive to communication(s) filed on 8/13/2004
- 2a) ☐ This action is **FINAL**. 2b) ☒ This action is non-final.
- 3) ☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

- 4) ☒ Claim(s) 89-91 is/are pending in the application.
- 4a) Of the above claim(s) _____ is/are withdrawn from consideration.
- 5) ☐ Claim(s) _____ is/are allowed.
- 6) ☒ Claim(s) 89-91 is/are rejected.
- 7) ☐ Claim(s) _____ is/are objected to.
- 8) ☐ Claim(s) _____ are subject to restriction and/or election requirement.

Application Papers

- 9) ☐ The specification is objected to by the Examiner.
- 10) ☐ The drawing(s) filed on _____ is/are: a) ☐ accepted or b) ☐ objected to by the Examiner.
Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).
Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).
- 11) ☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

Priority under 35 U.S.C. § 119

- 12) ☒ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).
- a) ☒ All b) ☐ Some * c) ☐ None of:
1. ☐ Certified copies of the priority documents have been received.
2. ☐ Certified copies of the priority documents have been received in Application No. _____.
3. ☒ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).
- * See the attached detailed Office action for a list of the certified copies not received.

Attachment(s)

- 1) ☐ Notice of References Cited (PTO-892)
- 2) ☐ Notice of Draftsperson's Patent Drawing Review (PTO-948)
- 3) ☐ Information Disclosure Statement(s) (PTO-1449 or PTO/SB/08)
Paper No(s)/Mail Date _____
- 4) ☐ Interview Summary (PTO-413)
Paper No(s)/Mail Date. _____
- 5) ☐ Notice of Informal Patent Application (PTO-152)
- 6) ☐ Other: _____

DETAILED ACTION

1. The finality of the last Office action is withdrawn. Claims 1-88 and 92-97 have been cancelled (8/13/2004). Amended claims 89-91 (8/13/2004) are pending and under consideration by the Examiner. Prosecution on the merits of this application is being re-opened on claims 89-91 considered unpatentable for the reasons indicated below.

Claim Rejections - 35 USC § 112, first paragraph, non-enablement

2. Claims 89-91 are rejected under 35 U.S.C. 112, first paragraph, as failing to comply with the enablement requirement. The claim(s) contains subject matter which was not described in the specification in such a way as to enable one skilled in the art to which it pertains, or with which it is most nearly connected, to make and/or use the invention.

The claims are drawn to methods of suppressing “differentiation” of undifferentiated cells. However, the specification fails to provide any guidance for the successful suppression of differentiation using serrate-1 peptide of SEQ ID NO:5, 6 or 7. The specification on pages 47-54 (Examples 10-13) and Figure 2A-2B disclose effects of the serrate-1 protein of SEQ ID NO:6 on suppressing colony formation in umbilical cord blood and bone marrow blood. However, the specification has disclosed examples of suppression of proliferation not differentiation, by the serrate-1 protein of SEQ ID NO:6. Suppression of proliferation is a completely different biological process from suppression of differentiation. In the instant specification the suppression of differentiation by the serrate-1 protein of SEQ ID NO:6 has not been enabled. One of skill in the art would have been unable to practice the invention in the absence of any guidance from the specification.

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The specification as filed does not provide any guidance or examples that would enable a skilled artisan to use the disclosed method. Additionally, a person skilled in the art would recognize that suppression of proliferation as measured by the number of colony forming units, is not predictive of suppression of differentiation (see MPEP §2164.02). Thus, although the specification discloses methodologies of suppression of proliferation in vitro by using the serrate-1 protein of SEQ ID NO:6, such a disclosure would not be enabling for a method for suppressing differentiation using the serrate-1 protein of SEQ ID NO:6, since the instant method as claimed is highly unpredictable and the experimentation that is necessary is undue. The test of enablement is whether one reasonably skilled in the art could make or use the invention from the disclosures in the patent coupled with information known in the art without undue experimentation. The factors listed below have been considered in the analysis of enablement [see MPEP §2164.01(a) and *In re Wands*, 858 F.2d 731, 737, 8 USPQ2d 1400, 1404 (Fed. Cir. 1988)]:

- (A) The breadth of the claims;
- (B) The nature of the invention;
- (C) The state of the prior art;
- (D) The level of one of ordinary skill;
- (E) The level of predictability in the art;
- (F) The amount of direction provided by the inventor;
- (G) The existence of working examples; and
- (H) The quantity of experimentation needed to make or use the invention based on the content of the disclosure.

Based on the evidence regarding each of the above factors, the instant specification, at the time the application was filed, would not have taught one skilled in the art how to make and use the claimed invention without undue experimentation. One would not have a reasonable expectation of successfully making and using the serrate-1 protein in the method as claimed.

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Claim Rejections - 35 USC § 112, second paragraph

3. Claims 89-91 are rejected under 35 U.S.C. 112, second paragraph, as being indefinite for failing to particularly point out and distinctly claim the subject matter which applicant regards as the invention.

Claims 89-91 are rejected as vague and indefinite because the limitation “undifferentiated blood cells” implies a cell in no differentiated state. However, all cells are in some state of differentiation. For example even a stem cell, is in a form of differentiation. Furthermore, there is a range of differentiated blood cells present in umbilical cord blood. On page 1, second para, first 3 lines of the specification, Applicants disclose “the undifferentiated blood cells are generally classified into two groups.....”. The recitation of “generally” implies that there may be other groups of undefined undifferentiated blood cells. Therefore, the metes and bounds of the term “undifferentiated blood cells” are unclear.

Conclusion

Claims 89-91 are rejected.

Advisory Information

Any inquiry concerning this communication or earlier communications from the examiner should be directed to Prema Mertz whose telephone number is (571) 272-0876. The examiner can normally be reached on Monday-Friday from 7:00AM to 3:30PM (Eastern time).

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Brenda Brumback, can be reached on (571) 272-0961.

Official papers filed by fax should be directed to (703) 872-9306. Faxed draft or informal communications with the examiner should be directed to (571) 273-0876.

Information regarding the status of an application may be obtained from the Patent application Information Retrieval (PAIR) system. Status information for published applications may be obtained from either Private PAIR or Public PAIR. Status information for unpublished applications is available through Private PAIR only. For more information about the PAIR system, see <http://pair-direct.uspto.gov>. Should you have questions on access to the Private PAIR system, contact the Electronic Business Center (EBC) at 866-217-9197 (toll-free).

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Prema Mertz
Prema Mertz Ph.D.
Primary Examiner
Art Unit 1646
August 25, 2004